

JUL 12 1999

K 991285

**510(k) SUMMARY**  
**AESCULAP-MEDITEC GMBH**  
**LASER SYSTEM RubyStar**  
**WITH NORMAL AND Q-SWITCH MODE**

This 510(k) summary of safety and effectiveness for the AESCULAP-MEDITEC GMBH Laser System RubyStar with normal and Q-Switch mode is submitted in accordance with the requirements of SDMA 1990 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant: AESCULAP-MEDITEC GMBH

Address: Prussingstrasse 41  
07739 Jena, Germany

Contact Person: Dr. Dirk Colditz  
Quality Management Representative

Phone: +49 3641 65 3453  
Fax: +49 3641 65 3815  
e-mail: [ctz@aesculap.meditec.com](mailto:ctz@aesculap.meditec.com)

Preparation date: March 1999

Device name: Laser System RubyStar

Common Name: RubyStar (with normal and Q-Switch mode)

**Classification**

Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)  
Product code: GEX – Laser instrument, surgical, powered  
Panel: 79

Legally marketed: MLT R694, LaseAway Long Pulse and Q-Switched Ruby Laser, MM-Ruby, Laser; Sectrum RD 1200; Candela AlexLazar

Description: The laser system RubyStar operates as a normal pulse or as a Q-Switched ruby laser which emits a beam of coherent light at 694 nanometers. In Q-Switched mode the beam has much shorter pulse duration than in the normal pulse mode.

Intended Use: The laser system RubyStar operating in normal mode is intended to remove unwanted body hair.  
The laser system RubyStar operating in Q-Switch mode is indicated for cutting, vaporization, or ablation of soft tissue. This includes tattoo removal and treatment of benign pigment lesions.

- Comparison to:** The specifications of the RubyStar laser in the Q-Switch mode are the same as or very similar to those of legally marketed lasers such as the MLT R694(Q-Switch mode), LaseAway Long Pulse and Q-Switched Ruby Laser, the MM-Ruby Laser; the Spectrum RD 1200, and the Candela AlexLAZR. The specifications of the RubyStar operating in normal mode are the same as or very similar to those of legally marketed lasers such as the MLT R694, EpiLaser, Chromos 694, and Sharplan EpiTouch.
- Performance data:** None. The specifications and intended uses of the laser system RubyStar operating in Q-Switch or normal mode are the same or very similar to those of claimed predicate devices. Because of this , performance data were not required.
- CONCLUSION:** When operating in Q-Switch or normal mode the RubyStar is substantially equivalent to legally marketed devices, e.g. ruby and alexandrite lasers, operating in both Q-Switch or normal mode.



JUL 12 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. William Kelley  
Aesculap-Meditec North America  
2525 McGaw Avenue  
Irvine, California 92623-9791

Re: K991285  
Trade Name: Laser System Ruby Star (with normal and Q-Switch mode)  
Regulatory Class: II  
Product Code: GEX  
Dated: March 31, 1999  
Received: April 15, 1999

Dear Mr. Kelley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

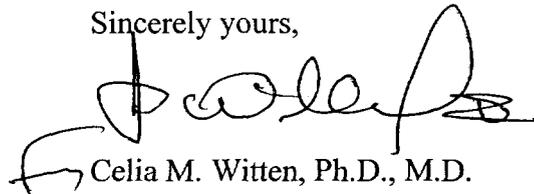
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. William Kelley

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K991285

Device Name: Laser System Ruby Star (with normal and Q-Switch mode)

Indications For Use Statement:

The laser system Ruby Star (operating in normal use) is intended to remove unwanted body hair.

The laser system Ruby Star (operating in Q-Switch mode) is indicated for cutting, vaporization, or ablation of soft tissue. This includes tattoo removal and treatment of benign pigmented lesions.

Some examples of pigment lesions are:

Lentigines, Cafe-au-lait-blotches, Ephalides, Benign Naevi such as Nevus of Ota, Naevus of Ito, Epidermal naevi, Congenital naevi, Becker's naevi, Blue naevus, Naevus spilus, and Mongolian spot.

The laser system Ruby Star is restricted to sale or use by licensed professionals in the United States

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter Use  
[Signature]  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991285